

NOV - 2 2011

1. 510(k) Summary

**FourSnare™ Vascular Retrieval Snare
510(k) Summary
21 CFR 807.92**

1. Submitter Information:

Applicant:	Cook Incorporated
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Phone Number:	(800) 468-1379
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Contact:	Molly Busenbark, MA, RAC
Contact Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47402
Contact Phone Number:	812-339-2235 Ext. 2162
Contact Fax Number:	812-332-0281

2. Device Information:

Trade name:	FourSnare™ Vascular Retrieval Snare
Common name:	Embolectomy catheter
Classification:	Class II
Regulation:	21 CFR 870.5150
Product Code:	MMX

3. Predicate Device:

Cook Incorporated's FourSnare™ Vascular Retrieval Snare, hereafter referred to as Vascular Retrieval Snare, or VRS, is substantially equivalent to the EN Snare Endovascular Snare System originally manufactured by Merit Medical under 510(k) clearance number K092343 and the Günther Tulip Vena Cava Filter Retrieval Set originally manufactured by Cook Incorporated under 510(k) clearance number K073374.

4. Comparison to Predicate Device:

It has been demonstrated that the Vascular Retrieval Snare is comparable to the predicate devices in terms of design, intended use, materials, fundamental technology, and principal of operation.

5. Device Description:

The Vascular Retrieval Snare consists of four petals composed of nitinol and tantalum. It is packaged with a coaxial sheath system and a dilator. Each of the sheaths of the coaxial system has radiopaque tips incorporated to identify the location of the distal tip of each sheath.

6. Intended Use:

The Vascular Retrieval Snare is intended for use in the cardiovascular system to manipulate and retrieve foreign objects, including, but not limited to, wire guides, coils, balloons, catheters, and filters.

7. Technological Characteristics:

The proposed Vascular Retrieval Snare contains a nitinol/tantalum snare basket (consisting of four loops) encased in a radiopaque TFE snare catheter, a nylon radiopaque inner sheath with radiopaque marker bands, a vinyl outer sheath with radiopaque marker bands and a polyethylene dilator. The nitinol/tantalum snare basket is used to manipulate and retrieve foreign objects from the vasculature. The technical characteristics of the VRS are substantially equivalent to the EN Snare Endovascular Snare System and the Günther Tulip Vena Cava Filter Retrieval Set because all three devices have components that function to manipulate and retrieve foreign objects from the vasculature.

The proposed Vascular Retrieval Snare was subjected to applicable testing to assure reliable design and performance under the testing parameters.

8. Test Data:

The following tests were performed to demonstrate that the Vascular Retrieval Snare meets applicable design and performance requirements and supports a determination of substantial equivalence. Additionally, appropriate engineering tests were also performed on aged product to ensure that the Vascular Retrieval Snare meets the performance requirements throughout the duration of shelf life.

- Tensile Strength – Testing shows the tensile strength during proper clinical use should not fracture or rupture the sheaths, catheter, or dilator. In conformance with

the applicable sections of ISO 11070 and ISO 10555-1, the predetermined acceptance criteria were met.

- Liquid Leakage – Testing shows there would be no liquid leakage from the catheter and sheath during proper clinical use. In conformance with the applicable sections of ISO 11070, the predetermined acceptance criteria were met.
- Simulated Use – Testing shows the the device can grasp foreign objects from a model to simulate clinical use. The predetermined acceptance criteria were met.
- Kink Radius – Testing shows the catheter, dilator, and sheaths should not kink during proper clinical use. The predetermined acceptance criteria were met.
- Opening and Closing the Basket Width – Testing shows the device can repeatedly open and close the basket width during proper clinical use. The predetermined acceptance criteria were met.
- Retraction Force – Testing shows that the snare can be retracted during proper clinical use. The predetermined acceptance criteria were met.
- Radiopacity – Testing shows that the applicable portions of the device shall be radiopaque during proper clinical use.
- Packaging Validation – Testing shows the packaging system shall maintain packaging integrity. The predetermined acceptance criteria were met.
- Biocompatibility – Testing shows the device is biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance that the device is as safe and effective as the predicate devices and supports a determination of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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Cook Inc.
c/o Ms. Molly Busenbark
750 Daniels Way
Bloomington, IN 47402

Re: K112185

Trade/Device Name: Four Snare Vascular Retrieval Snare
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II (two)
Product Code: MMX
Dated: October 12, 2011
Received: October 13, 2011

Dear Ms. Busenbark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

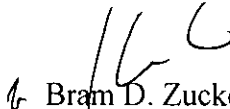
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Cook Incorporated
FourSnare™ Vascular Retrieval Snare Traditional 510(k)
12 October 2011

4. Indications for Use Statement

510(k) Number (if known): K112185

Device Name: FourSnare™ Vascular Retrieval Snare

Indications for Use:

The Vascular Retrieval Snare is intended for use in the cardiovascular system to manipulate and retrieve foreign objects, including, but not limited to, wire guides, coils, balloons, catheters, and filters.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112185

Concurrence of CDRH, Office of Device Evaluation (ODE)